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COMMENT

Wrong Price, Wrong Prescription: Why Maryland's Generic Drug Law Was Not Enough to Effect Change in Rising Prescription Drug Prices

By: Mario B Davis *

I. Introduction

A recent spike in pricing of prescription drugs has sparked public concern.¹ The price of medication has been rising steadily in recent years, including a few high-profile examples of drastic price increases.² As a result, the U.S. spent \$450 billion on prescription drugs in 2016, an increase of 5.8 percent from 2015.³ Maryland residents spent upwards of six billion dollars on prescription drugs in 2016.⁴

The continued rising cost of prescription drugs is an issue that hits home for many Americans, with forty nine percent nationwide reporting they took a prescription drug within the last thirty days.⁵ Prices of popular drugs like

*J.D. Candidate, 2019, University of Baltimore School of Law. I would like to thank my faculty advisor, John Lynch, Jr., for his guidance and critiques during my drafting process. I would also like to thank the entire *University of Baltimore Law Forum* staff for all of their hard work editing this comment. Finally, I would like to thank my parents and my brother for their tireless support throughout my law school career.

¹ Inmaculada Hernandez et al., *The Contribution of New Product Entry Versus Existing Product Inflation In The Rising Costs of Drugs*, HEALTH AFFAIRS 76(January, 2019), <https://scholar.harvard.edu/files/cutler/files/hlthaff.2018.05147.pdf>.

² Aaron S. Kesselheim, MD, JD, MPH, Jerry Avron, MD, Ameet Sarptwari, JD, PhD, *The High Cost of Prescription Drugs in the United States: Origins and Prospects for Reform*, JAMA (last visited April 19, 2019), <https://phhp-bahealthscience-new.sites.medinfo.ufl.edu/files/2016/09/jsc1600151.pdf>; See generally Andrew Pollack, *Drug Goes From \$13.50 a Tablet to \$750, Overnight*, THE NEW YORK TIMES (Nov. 18, 2017 5:20 PM), <https://www.nytimes.com/2015/09/21/business/a-huge-overnight-increase-in-a-drugs-price-raises-protests.html>.

³ Bill Berkrot, *U.S. Prescription Drug Spending as High as \$610 Billion by 2021*, REUTERS (May 4, 2017 12:46 AM), <https://www.reuters.com/article/us-usa-drugspending-quintilesims/u-s-prescription-drug-spending-as-high-as-610-billion-by-2021-report-idUSKBN1800BU>

⁴ *Total Sales for Prescription Drugs Filled at Pharmacies: Maryland*, KISER FAMILY FOUNDATION (last visited April 19, 2019), <https://www.kff.org/health-costs/state-indicator/total-sales-for-retail-rx-drugs/?currentTimeframe=0&selectedRows=%7B%22states%22:%7B%22maryland%22:%7B%7D%7D%7D&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7Dstates%22:%7B%7D%7D%7D&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D>.

⁵ Katie Beyer, *Drug Money Part 2: A Look at 2017 State Legislative Efforts to Reduce Prescription Drug Prices*, THE SOURCE BLOG ON HEALTH CARE (Aug. 3, 2017),

insulin tripled between 2002 and 2013.⁶ Similarly, the price for an EpiPen has risen 500 percent since 2007.⁷

In 2017, Maryland joined forty-three other states' that have enacted legislation aimed at combating high drug prices by introducing House Bill 631 ("HB631").⁸ In an attempt to address the concern in the rising costs of prescription drugs, Maryland enacted the Essential Off-Patent or Generic Drug Price Gouging Prohibition Act ("MD Price-Gouging Act"), which prohibits price gouging of "essential off-patent or generic drugs."⁹ In the bill, price gouging is defined as "any unconscionable increase in the price of a generic prescription drug sold in Maryland that is not justified by the cost of production or expansion of access and results in no meaningful choice for customers to purchase the drug."¹⁰ The law specifically attempted to target manufacturers who have historically hiked the prices of generic drugs with no market competition.¹¹ Companies manufacturing new drugs would not be included, nor would a majority of generic drug manufacturers who have participated in competitive markets to help drive their prices down.¹²

This comment will address the issue of rising prescription drugs costs, and explore Maryland's recent attempt at combating high drug prices. Part II will analyze the M.D. Price-Gouging Act and how it attempted to combat the issue of rising off-patent drug prices. Part III explains how the high cost of prescription drugs is affecting Maryland consumers, as well as the recent litigation over the Prohibition Against Price Gouging for Essential off-Patent or Generic Drugs (herin after "the Maryland Price Gouging Act"). Finally, Part IV will first discuss potential federal solutions, and then it will advocate for amending the MD Price-Gouging Act to compel companies to notify the state of impending price increases.

http://sourceonhealthcare.org/drug-money-part-2-a-look-at-2017-state-legislative-efforts-to-reduce-prescription-drug-prices/#_ftn5.

⁶ Robert Love, *Why Drugs Cost So Much*, AARP Bulletin (May 1, 2017), <https://www.aarp.org/health/drugs-supplements/info-2017/rx-prescription-drug-pricing.html>.

⁷ *Id.*

⁸ *Id.*

⁹ MD. CODE ANN., HEALTH § 2-803 (LexisNexis 2017).

¹⁰ *Id.* at § 2-801 (f).

¹¹ *Id.*

¹² Jeremy A. Green, MD, PhD & William V. Padula, PhD, *Targeting Unconscionable Prescription-Drug Prices – Maryland's Anti-Price-Gouging Law*, NEW ENGLAND JOURNAL OF MEDICINE (October 14, 2017 3:20 PM) <https://catalyst.nejm.org/marylands-anti-price-gouging-law/>.

II. HISTORICAL DEVELOPMENT

A. *Current Law in Maryland*

The Maryland Consumer Protection Act (“MCPA”) was implemented in 1973 to provide a private cause of action for consumers harmed by unfair and deceptive trade practices.¹³ To this day, the MCPA is the only current protection for Maryland residents regarding prescription drug prices. The stated intent of the MCPA is to “provide minimum standards for the protection of consumers in the State.”¹⁴ Mainly, the MCPA protects against unfair or deceptive trade practices such as “any false, falsely disparaging, or misleading oral or written statement, visual depiction, or other representation of any kind, which has the capacity, tendency, or effect of deceiving or misleading consumers.”¹⁵

Unfortunately, the MCPA falls short of protecting Maryland consumers from skyrocketing prescription drug prices. A 2010 audit of the MCPA by the Maryland Department of Health and Mental Hygiene (“DHMH”) discovered that the Act did not ensure that pricing information of drugs was reasonable.¹⁶ While the DHMH audit did acknowledge that drug prices are comprised of various components, they discovered that Pennsylvania’s Medicaid Program contracted three different vendors to assess the reasonableness of drug prices.¹⁷ Furthermore, the audit found that the company used by the MCPA to obtain pricing data recently settled a lawsuit, and was involved in litigation with several entities that allege it colluded with a drug manufacturer to inflate drug prices.¹⁸

The DHMH ultimately recommended that the MCPA identify measures to ensure pricing data is evaluated and compared to other prices for reasonableness.¹⁹ The reasonableness comparison was added in an attempt to make the law more enforceable against price increases; however, it still did not do enough. Maryland’s recent attempt at legislation attempted to combat this issue head on, though it fell short of this goal.

¹³ See generally MD. CODE ANN., COMMERCIAL LAW § 13-301 (LexisNexis 2017).

¹⁴ MD. CODE ANN., COMMERCIAL LAW § 13-103 (a) (LexisNexis 2017).

¹⁵ *Id.* at § 13-301.

¹⁶ See generally MARYLAND GENERAL ASSEMBLY OFFICE OF LEGISLATIVE AUDITS, DEPARTMENT OF HEALTH AND MENTAL HYGIENE MEDICAL CARE ASSISTANCE PROGRAMS ADMINISTRATION AUDIT REPORT 9 (December, 2010).

¹⁷ *Id.*

¹⁸ *Id.*

¹⁹ *Id.*

B. Senate Panel Investigates Four Pharmaceutical Companies

In 2011, Maryland Congressman Elijah Cummings led an effort to release congressional reports on pharmaceutical pricing.²⁰ In direct response to several independent reports, Congressmen Cummings spearheaded an investigation into drug speculation practices of five companies alleged to be raising prices of drugs in critically short supply.²¹ These reports were precursors to the more recent reports focused on off-patent drug pricing.

The first report, entitled “Sudden Price Spikes in Off-Patent Prescription Drugs: The Monopoly Business Model that Harms Patients, Taxpayers, and the U.S. Health Care System,” was issued by the U.S. Senate’s bipartisan Special Committee on Aging.²² The report was the product of a Senate investigation of “abrupt and dramatic price increases in prescription drugs whose patents had expired long ago.”²³

The committee evaluated four companies: Turing Pharmaceuticals; Retrophin, Inc.; Valeant Pharmaceuticals International, Inc.; and Rodelis Therapeutics. All recently purchased decades-old off-patent drugs, and raised the prices suddenly.²⁴ The report describes a business model in which companies produce a drug serving a small market as the only manufacturer to ensure the drug is the best on the market for the condition it treats.²⁵ This controls access to the drug and allows the companies to engage in “price gouging” by increasing prices as high as possible.²⁶ The report further provided illustrations such as Retrophin’s increase of Thiola, a kidney

²⁰ Cummings Investigates Potential Prescription Drug Price Gouging, HOUSE COMMITTEE ON OVERSIGHT AND GOVERNMENT REFORM (March 6, 2018), <https://democrats-oversight.house.gov/cummings-investigates-potential-prescription-drug-price-gouging>.

²¹ *Id.*; See also Coleen Cherici, Patrick McGinnis, Wayne Russell, Buyer beware: Drug shortages and the gray market, PREMIER HEALTHCARE ALLIANCE (last visited April 18, 2019), <http://www.anco-online.org/GrayMarketAnalysis-Premier.pdf>; ISMP Survey on Drug Shortage “Gray Market” Shows Widespread Impact on Hospitals, INSTITUTE FOR SAFE MEDICATION PRACTICES (Aug. 25, 2011), <https://forms.ismp.org/pressroom/PR20110825.pdf>.

²² STAFF OF S. COMM. ON AGING, 114TH CONG., SUDDEN PRICE SPIKES IN OFF-PATENT PRESCRIPTION DRUGS: *THE MONOPOLY BUSINESS MODEL THAT HARMS PATIENTS, TAXPAYERS, AND THE U.S. HEALTH CARE SYSTEM* (Comm. Print 2016).

²³ *Id.* at 3.

²⁴ *Id.* (mentioning that Retrophin has appeared to reverse this business model after Mr. Shkreli).

²⁵ *Id.*

²⁶ *Id.* at 4.

medicine, from \$1.50 to \$30.00 per pill, and Rodelis's price increase of 30 capsules of Seromycin, a tuberculosis medication, from \$500 to \$10,800.²⁷

The second report was issued by the Government Accountability Office and studied a group of 1,441 established generic drugs.²⁸ The study found that between 2010 and 2015, manufacturers had imposed at least one "extraordinary price increase" for over 300 of those drugs.²⁹ Additionally, of those drugs, forty-eight had increases of 500 percent or higher, and fifteen had increases of 1000 percent or higher.³⁰

C. *Essential Generic Drug Price-Gouging Prohibition*

In response to these reports, HB631 was introduced in early 2017, passing both houses of the Maryland General Assembly by large bipartisan majorities. The Governor of Maryland, Larry Hogan, declined to sign the bill, citing constitutional issues.³¹

The MD Price Gouging Act has two primary functions. First, it prohibits manufacturers or wholesale distributors from engaging in price gouging in the sale of an "essential off-patent or generic drug."³² Under the act, an essential off-patent or generic drug is any prescription drug free from "exclusive marketing rights under the Federal Food, Drug and Cosmetic Act, that appears on the World Health Organization's model list of essential medicines or is designated by the Secretary of Health and Mental Hygiene as an essential medicine."³³ The act additionally requires generic drugs be actively marketed in the United States by three or fewer manufacturers and be available for sale in Maryland.³⁴

"Price gouging" is an unconscionable increase in the price of a prescription drug.³⁵ "Unconscionable Increase" refers to an increase in the price of a prescription drug that is:

²⁷ *Id.* at 4-6.

²⁸ Generic Drugs Under Medicare, Comp. Gen., 1, 14 (2016).

²⁹ *Id.*

³⁰ *Id.*

³¹ Letter from Gov. Larry Hogan, Governor of Md., to Hon. Michael E. Busch, Md. Speaker of the House (May 26, 2016) (stating the bill could have dormant commerce and 14th Am. due process issues.).

³² MD. CODE ANN., HEALTH § 2-802 (LexisNexis 2017) (repealed 2018).

³³ *Id.* at § 2-801.

³⁴ *Id.*

³⁵ *Id.*

(1) excessive and not justified by the cost of producing the drug or the cost of appropriate expansion of access to the drug and (2) results in consumers having no meaningful choice of whether or not to purchase the drug at a higher price due to the importance of the drug to their health and lack of market competition.³⁶

A wholesale distributor may increase the price of an essential generic drug if the price increase is directly attributable to additional costs for the drug imposed on the wholesale distributor.³⁷

The second primary function of the act is to authorize the Maryland Medical Assistance Program (“MMA”) to notify the Attorney General (“AG”) of any price increase.³⁸ First, MMA allows the AG to be notified when the price increase (by itself or in combination with other price increases) would result in an increase of fifty percent or more in the wholesale acquisition cost of the drug within the preceding one-year period, or the price paid by Medicaid for the drug within the preceding one year period.³⁹ Additionally, MMA may notify the AG of the price increase in one of three situations. First, if a thirty-day supply of the maximum recommended dosage, according to the label for the drug approved under FDCA, would cost over \$80 at the drugs wholesale acquisition cost.⁴⁰ Second, The AG may also be notified if a full course of treatment of the drug approved under FDCA, would cost more than \$80 at the drugs wholesale acquisition cost.⁴¹ Finally, if the drug is made available to consumers only in quantities that do not include a thirty-day supply, a full course of treatment, or a single dose, and it would cost more than \$80 at the drug’s wholesale acquisition cost to obtain a 30-day supply or a full course treatment.⁴²

The advantages of Maryland’s The MD Price Gouging Act showed a stark contrast to those of the MCPA. Advocates celebrated the increased discretion for the Maryland Attorney General to sue companies for unwarranted price hikes.⁴³ Additional advantages include the AG’s ability to reverse price hikes, impose fines on the companies said to violate to law and return some funds to

³⁶ *Id.*

³⁷ *Id.* at § 2-802.

³⁸ MD. CODE ANN., HEALTH § 2-803 (LexisNexis 2017).

³⁹ *Id.*

⁴⁰ *Id.*

⁴¹ *Id.*

⁴² *Id.*

⁴³ Diane Archer, Maryland law protects people from prescription drug price gouging, JUST CARE (June 14, 2017), <http://justcareusa.org/maryland-law-protects-people-from-prescription-drug-price-gouging/>.

consumers taking the drugs who have been victims of the price hikes.⁴⁴ Some critics viewed the AG's new powers as roll back of his previous abilities, because it limits the power to act only for non-competitive drugs and stipulates that companies must be given time to correct the price hike.⁴⁵ Regardless, these new provisions could have allowed for meaningful punishments for drug companies who unnecessarily hike their prices, and also provide some monetary relief for patients who suffer from these price hikes.

On the other hand, many opponents to the law have leaned on the idea that the law simply was not definitive enough to allow manufacturers to know when they have violated the law. In their reply brief, the Association for Affordable Medicines ("AAM") notes that appellee's have not once given a straight answer as to whether even a ten percent increase would be "unconscionable".⁴⁶ This disadvantages companies affected by the law because it decreases the incentive for competition in the market, which only drives prices higher, creating the ability for more companies to violate the law.⁴⁷

III. ISSUE/PROBLEM

A. *Challenges to the Prohibition Against Price Gouging for Essential Off-Patent or Generic Drugs*

Maryland's groundbreaking law came with some major pushback.⁴⁸ Shortly after its passage in July of 2017, the AAM filed a complaint seeking declaratory and injunctive relief to bar the enactment of the law.⁴⁹ In response, the Attorney General for Maryland moved to dismiss the claim.⁵⁰

⁴⁴ *Id.*

⁴⁵ Green & Padula, *supra* note 12.

⁴⁶ Reply Brief for Appellant at 19, *Ass'n for Accessible Meds v. Frosh*, 887 F.3d 664 (D. Md. 2017)(No. 17-2166), 2017 WL 6402860, at *19.

⁴⁷ Green & Padula, *supra* note 12.

⁴⁸ See generally Erin Cox, Drug Firms Challenge Maryland's price-gouging law, THE BALTIMORE SUN (December 27, 2017) <http://www.baltimoresun.com/news/maryland/politics/bs-md-price-gouging-suit-20170706-story.html>; *Ass'n for Accessible Meds v. Frosh*, No. MJG-17-1860 (D. Md. September 29, 2017).

⁴⁹ See generally Pl.'s Mot. Prelim. Inj., *Ass'n for Accessible Meds v. Frosh*, (D. Md. Jul. 6, 2017) (No. 1:17-cv-1860), 2017 WL 2884401.

⁵⁰ See generally Defs.' Mot. Dismiss, *Ass'n for Accessible Meds v. Frosh*, No. 17-1860-MJG (D. Md. 2017), 2017 WL 9438490.

The initial hurdle arose when the bill first came across Governor Larry Hogan's desk.⁵¹ The Governor believed the bill did not do enough to protect all drug pricing, while at the same time citing the same constitutional issues found in plaintiff's complaint.⁵² According to Governor Hogan, the legislation did nothing to address the rising cost of patented products and "medical devices which may be associated with drug delivery."⁵³ He argued that the bill should do more for patented drugs, since they make up a significant portion of the market.⁵⁴ Ultimately, he refused to sign it, but allowed it to become law after expressing his concerns.⁵⁵

Plaintiff's complaint raised two primary causes of action.⁵⁶ AAM first alleged HB 631 is unconstitutional under the Commerce Clause because the State of Maryland is discriminating against interstate commerce.⁵⁷ The primary purpose of the Commerce Clause is to regulate "commerce with foreign Nations, and among the several States;" however, it also prohibits states from discriminating against interstate commerce.⁵⁸

The long established "dormant command" in the Commerce Clause prohibits each state from regulating extraterritorial economic activity.⁵⁹ The Supreme Court has long viewed the Commerce Clause as "an implicit restraint on state authority, even in the absence of a conflicting federal statute."⁶⁰ The primary factor used in determining if a statute violates the commerce clause "is whether the practical effect of the regulation is to control conduct beyond the boundaries of the State."⁶¹

Ultimately, AAM alleged HB 631 violates two well established precedents. First, a state law which regulates commercial activity occurring completely outside of the State's borders exceeds the limits of State's authority and will generally not succeed "whether or not the regulated commerce has effects

⁵¹ Letter from Gov. Larry Hogan, *supra* note 31.

⁵² *Id.*

⁵³ *Id.*

⁵⁴ *Id.*

⁵⁵ *Id.*

⁵⁶ See generally Pl.'s Mot. Prelim. Inj, *Ass'n for Accessible Meds v. Frosh*, (D. Md. Jul. 6, 2017) (No. 1:17-cv-1860), 2017 WL 2884401.

⁵⁷ *Id.*

⁵⁸ U.S. Const. art. I, § 8, cl. 3.

⁵⁹ Pl.'s Mot. Prelim. Inj. at 6.; *Okla. Tax Comm'n v. Jefferson Lines, Inc.*, 514 U.S. 175, 179 (1995).

⁶⁰ *United Haulers Ass'n, Inc. v. Oneida-Herkimer Solid Waste Mgmt. Auth.*, 550 U.S. 330, 338 (2007); See also U.S. Const. art. I, § 8, cl. 3 ("The Congress shall have Power ... [t]o regulate Commerce with foreign Nations, and among the several States, and with the Indian Tribes.").

⁶¹ *Healy v. Beer Inst.*, 491 U.S. 324, 336 (1989).

within the State.”⁶² Similarly, AAM further argued that a State may not attempt to control the price of a good within its borders by regulating the price of transactions that occur outside of the State.⁶³

AAM stated that HB 631 violates the Commerce Clause because it attempts to directly regulate prices for transactions, which sometimes largely occur outside of the state.⁶⁴ The bill is not limited to commerce that occurs within Maryland, or even sales that occur between an entity outside of Maryland and an entity within it.⁶⁵ Instead, it prohibits generic drug manufacturers and wholesale distributors from “unconscionably” raising the price of any of their essential generic drug that is available for sale in the State, even if the manufacturer or wholesale distributor never directly dealt with a consumer residing in the State.⁶⁶

AAM particularly takes issue with the extra territorial reach of HB 631. Manufacturers sell the majority of off patent and generic prescription drugs to either large wholesalers or large retail pharmacy chains that warehouse their own drugs.⁶⁷ However, of the three largest wholesalers in the country, which account for ninety percent of the national wholesale market, none reside in Maryland.⁶⁸ Only one of the nation’s twenty largest generic drug manufactures is headquartered in Maryland, and none of them actually manufacture drugs in the state.⁶⁹ AAM’s argues that a large portion of off-patent and generic prescription drugs are only made available for sale in the State of Maryland under specific circumstances.⁷⁰

In AAM’s view, HB 631 represented an overreach by the Maryland State legislature which is forbidden by the Dormant Commerce Clause.⁷¹ Manufacturers and wholesalers can violate the terms of the law even if they engage in no direct commercial activity in Maryland at all, because they don’t sell directly to Maryland consumers.⁷² This discourages companies from

⁶² *Healy*, 491 U.S. at 336.

⁶³ See generally *Baldwin v. G.A.F. Seelig, Inc.*, 294 U.S. 511, 523 (1935) (“[A] State may not adopt legislation that has the practical effect of establishing ‘a scale of prices for use in other states.’”).

⁶⁴ Pl.’s Mot. Prelim. Inj. at 9.

⁶⁵ *Id.*

⁶⁶ Pl.’s Mot. Prelim. Inj. at 9; § 2-801(b)(1)(iv); § 2-803(g).

⁶⁷ Pl.’s Mot. Prelim. Inj. at 9.

⁶⁸ *Id.* at 10; RxCommercial Research International, Inc., Investing into BioPharma Products in the USA (Color): A Reference Guide 156 (2012).

⁶⁹ *Id.*

⁷⁰ *Id.* (Explain process for how to sell drugs in MD #52 Complaint.).

⁷¹ *Id.*

⁷² *Id.*

conducting commerce outside of Maryland due to the potential liability they will face in the state, even for sales that occur outside of the state.⁷³ AAM's motion argued that the law has the practical effect of establishing "a scale of prices for use in other states," and should be void.⁷⁴

AAM next contended that HB 631 should be held void for vagueness in accordance with the 14th Amendment Due Process Clause.⁷⁵ The Fourteenth Amendment prohibits states from depriving "any person of life, liberty, or property without due process of law."⁷⁶ Laws that fail to inform a person of "ordinary intelligence" exactly what is prohibited violate this requirement of due process, and are void for vagueness.⁷⁷ The Supreme Court has consistently held, "a statute which either forbids or requires the doing of an act in terms so vague that men of common intelligence must necessarily guess at its meaning . . . violates the first essential of due process of law."⁷⁸ Vague laws can have the effect of trapping innocent consumers by not providing fair warning.⁷⁹ This requirement of clarity in regulation is essential to the protections provided by the Due Process Clause.⁸⁰

AAM also alleged that HB 631 fails to provide a meaningful description of what its terms proscribe.⁸¹ Civil statutes will normally be deemed unconstitutionally vague only if the terms are "so vague and indefinite as really to be no rule or standard at all."⁸² This standard requires that an economic legislation be invalidated if it does not at least establish minimal guidelines to govern officials or give reasonable notice of the conduct prohibited.⁸³ HB 631's language prohibited price gouging, which it defines as "increase[ing] the price of a prescription drug" in a manner that is excessive and not cost-justified, leaving consumers with no meaningful choice about whether to

⁷³ *Id.*; *Pharm. Research & Mfrs. of Am. v. District of Columbia*, 406 F. Supp. 2d 56, 70 (D.D.C. 2005).

⁷⁴ *Id.*

⁷⁵ *See generally Id.*

⁷⁶ U.S. Const. amend. XIV, § 1.

⁷⁷ *Grayned v. City of Rockford*, 408 U.S. 104, 108 (1972).

⁷⁸ *Connally v. Gen. Constr. Co.*, 269 U.S. 385, 391 (1926); *See also FCC v. Fox Television Stations, Inc.*, 132 S. Ct. 2307, 2317 (2012) ("A fundamental principle in our legal system is that laws which regulate persons or entities must give fair notice of conduct that is forbidden or required.")

⁷⁹ *Grayned*, 408 U.S. at 108.

⁸⁰ *See generally Connally*, 269 U.S. at 391 (citing *International Harvester Co. v. Kentucky*, 234 U.S. 216, 221, 34 S. Ct. 853, 58 L. Ed. 1284 (1914); *Collins v. Kentucky*, 234 U.S. 634, 638, 34 S. Ct. 924, 58 L. Ed. 1510 (1914)).

⁸¹ Pl.'s Mot. Prelim. Inj. at 11.

⁸² *Ass'n of Int'l Auto. Mfrs. v. Abrams*, 84 F.3d 602, 614 (2d Cir. 1996).

⁸³ *Schleifer by Schleifer v. City of Charlottesville*, 159 F.3d 843, 853 (4th Cir. 1998).

purchase the drug at an excessive price.⁸⁴ However, the bill provided no further guidance as to how to interpret or apply the provisions. The law provided no way for manufacturers and wholesale distributors to determine whether a price is “excessive”, whether a price increase is “appropriate”, or whether a particular consumers options for medicine are “meaningful”.

Furthermore, AAM took issue with the broad powers given to the AG when deciding whether or not to launch an investigation or lawsuit.⁸⁵ The definitions of the terms justified, appropriate, excessive, and meaningful are left entirely to the discretion of the AG.⁸⁶ The AG was a vocal proponent of the bill, and AAM was concerned that the loose terminology gives the AG wide latitude for enforcement.⁸⁷ The AG acknowledged AAM’s concerns but stated that his office “can only focus on the most egregious cases because of how the bill is written and limited resources.”⁸⁸ This lack of clarity and direction of the AG’s enforcement created an issue concerning the potential monetary penalties associated with a violation of the law.⁸⁹ Accordingly, AAM argued HB631 failed to provide off-patent and generic drug companies “reasonable notice” of prohibited conduct and failed to establish “minimum guidelines to govern official’s exercise of discretion in implementing and enforcing it.”⁹⁰

AAM’s arguments hold some merit given case law on the commerce clause issue. In *Baldwin v. G.A.F. Seeling Inc.*, the Supreme Court invalidated a New York law that regulated an out-of-state transaction triggered by a sale occurring within the state.⁹¹ The act prohibited the sale of milk purchased outside of the state of New York unless the price paid to the out of state producers was similar to that of a transaction with an in-state producer.⁹² This law was passed in an effort to incentivize New York milk dealers to buy from in-state producers and was only triggered once the milk was actually sold in the state.⁹³ In this case, the plaintiff was a New York milk dealer who

⁸⁴ Pl.’s Mot. Prelim. Inj. at 11; § 2-802(a); § 2-8021(f).

⁸⁵ Pl.’s Mot. Prelim. Inj. at 11.

⁸⁶ *Id.*

⁸⁷ *Id.*

⁸⁸ Families USA, Prescription Drug Price Gouging: Maryland’s Landmark Law Protects Consumers (May 30, 2017), <http://familiesusa.org/blog/2017/05/prescription-drug-price-gouging-maryland-landmark-law-protects-consumers>.

⁸⁹ Pl.’s Mot. Prelim. Inj. at 12, *Ass’n for Accessible Meds v. Frosh*, (D. Md. Sept. 29, 2017) (No. MJG-17-1860), 2017 WL 4347818.

⁹⁰ *Id.*

⁹¹ *Baldwin*, 294 U.S. at 511.

⁹² *Id.* at 519.

⁹³ *Id.*

purchased milk from a Vermont creamery, who got their milk from producers on Vermont farms.⁹⁴ The Supreme Court determined the law violated the established commerce clause doctrine by effectively regulating the out of state price of milk sold in New York.⁹⁵ The Court found that New York was essentially using an in-state hook, (i.e. sale of the milk in New York) to affect out of state conduct and pricing.⁹⁶

The New York act at issue in *Baldwin* has one major difference compared to Maryland's law. In *Baldwin*, violation of the act was triggered by an actual sale within the state of New York, otherwise known as an "as applied challenge."⁹⁷ In contrast, Maryland's law is only effective if the drug is available for sale in Maryland but does not require an actual sale of the drug to trigger relief.⁹⁸ In other words, the Maryland law is being challenged on its face as unconstitutional. Though the act at issue in *Baldwin* was ultimately unsuccessful, the analysis would be inapplicable to Maryland's new law.

B. Current Litigation

In September of 2017, the United States District Court for the District of Maryland heard arguments in the case *Ass'n for Accessible Meds. v. Frosh* to address AAM's constitutional challenges to HB 631.⁹⁹ Specifically, the court examined whether or not the new law violated the Dormant Commerce Clause and the Fourteenth Amendment vagueness standard.

The court used a two-tiered analysis to determine whether a state statute violated the Dormant Commerce Clause.¹⁰⁰ The first tier dictates that a state statute is usually struck down "without further inquiry" when it directly regulates or discriminates against interstate commerce, or favors in-state economic interests over out-of-state interests.¹⁰¹ When a statute "regulates even handedly", the court moves to the second tier analysis, looking to "whether the State's interest is legitimate and whether the burden on interstate commerce clearly exceeds local benefits."¹⁰² Additionally, recent Supreme

⁹⁴ *Baldwin*, 294 U.S. at 519.

⁹⁵ *Id.*

⁹⁶ *Id.*

⁹⁷ *Id.*

⁹⁸ § 2-801.

⁹⁹ *Ass'n for Accessible Meds v. Frosh*, No. MJG-17-1860, 2017 WL 4347818 (D. Md. 2017).

¹⁰⁰ *Brown-Forman Distillers Corp. v. New York State Liquor Auth.*, 476 U.S. 573, 579, 106 S. Ct. 2080, 90 L. Ed. 2d 552 (1986); *Star Scientific Inc. v. Beales*, 278 F.3d 339, 355 (4th Cir. 2002).

¹⁰¹ *Brown-Forman*, 476 U.S. at 579.

¹⁰² *Id.*

Court precedent has created a “third strand” of analysis, referred to as the “extraterritoriality principle”.¹⁰³ This analysis is specifically applied to price control laws that control conduct outside of states borders.¹⁰⁴

The United States District Court for Maryland held that AAM did not allege a plausible Dormant Commerce Clause violation under the first tier or the “extraterritoriality principle.”¹⁰⁵ AAM argued that HB 631 impermissibly regulates conduct occurring wholly outside of Maryland by controlling pricing of manufacturers and wholesalers who do not sell directly to actors in Maryland.¹⁰⁶ According to the court, HB 631 limited its regulation to drug manufacturers or wholesalers selling off-patent or generic drugs “made available for sale in the State.”¹⁰⁷ Therefore, the law did not reach those manufactures or wholesalers whose drug will not, at some point, become available for sale in Maryland.¹⁰⁸ Though HB 631 could affect prices charged by out-of-state distributors, the effect would only be applied to prices on drugs sold within Maryland.¹⁰⁹ The court further held that since HB 631 does not tie the price charged in the sales of in-state drugs with the price charged on drugs sold out-of-state, it does not have the “practical effect” of regulating commerce occurring wholly outside of the state.

As for the second tier balancing test, the court also held that AAM failed to allege a plausible claim.¹¹⁰ Under this test, if the statute regulates evenly to create a legitimate local public interest, and it has only incidental effects on interstate commerce, it will be upheld “unless the burden imposed on such commerce is clearly excessive in relation to the presumed local benefits.”¹¹¹ Defenders stated their legitimate interest in enforcing HB 631 was to prevent price-gouging in Maryland for essential medicines and to protect the health

¹⁰³ *Ass’n for Accessible Meds v. Frosh*, No. MJG-17-1860, 2017 WL 4347818 (D. Md. 2017) at 8.

¹⁰⁴ *Energy & Env’t Legal Inst. V. Epel*, 793 F.3d 1169, 1172 (10th Cir. 2015), *cert. denied*, 136 S. Ct. 595, 193 L. Ed. 2d 487 (2015).

¹⁰⁵ *Ass’n for Accessible Meds v. Frosh*, No. MJG-17-1860, 2017 WL 4347818 (D. Md. 2017) at 20.

¹⁰⁶ *Id.* at 13.

¹⁰⁷ MD. CODE ANN., HEALTH § 2-801 (b)(1) (LexisNexis 2017).

¹⁰⁸ *Id.*

¹⁰⁹ *Ass’n for Accessible Meds v. Frosh*, No. MJG-17-1860, 2017 WL 4347818 (D. Md. 2017) at 14.

¹¹⁰ *Id.* at 21.

¹¹¹ *Id.* at 20; *See generally Yamaha Motor Corp., U.S.A. v. Jim’s Motorcycle, Inc.*, 401 F.3d 560, 567 (4th Cir. 2005).

and safety of Maryland residents.¹¹² AAM presented no arguments to refute the validity of this legitimate interest. Ultimately, the court held that given the state's strong interest in protecting its residents, and since AAM had presented no evidence to show that "the burden on interstate commerce would clearly exceed the local benefits", the challenge cannot succeed under this test.¹¹³ In a later entry of final judgment, the court dismissed all claims relating to the Dormant Commerce Clause.¹¹⁴

The Supreme Court has struck down statutes similar to HB 631 under the first tier of analysis and the extra territoriality principle.¹¹⁵ In *Brown-Forman*, the Court invalidated a provision of a New York law requiring liquor distillers selling within the state to affirm that their prices for products sold in state were not higher than the lowest price that the same product was sold for in any other state during that month.¹¹⁶ Forcing a merchant to seek approval in one state before transacting in another directly regulates interstate commerce.¹¹⁷ In this case, once a distiller's posted price takes effect in New York, the New York State Liquor Authority must approve the price before it may lower its price for the same item in other States.¹¹⁸ Though the statute did limit itself only to the sale of liquor in New York, the court found it had the "practical effect" of controlling the price of liquor in other states.¹¹⁹

In *Healy*, the Court invalidated the Connecticut Liquor Control Act under the Commerce Clause.¹²⁰ Much like in *Brown-Forman*, the act required out of state beer shippers to affirm that the prices of their products sold to Connecticut wholesalers weren't higher than the prices of the same products sold in bordering states.¹²¹ The Court reasoned that since the law forces out of state beer shippers to seek approval for their prices before selling in another state, the law was in direct violation of the Commerce Clause.¹²²

More analogously, the structure of HB 631 is similar to the Virginia statute at issue in *Star Scientific Inc.*¹²³ That statute required cigarette manufacturers

¹¹² *Ass'n for Accessible Meds v. Frosh*, No. MJG-17-1860, 2017 WL 4347818 (D. Md. 2017) at 7.

¹¹³ *Id.*

¹¹⁴ *See generally Ass'n for Accessible Meds v. Frosh*, No. MJG-17-1860, 2017 WL 4347818 (D. Md. 2017).

¹¹⁵ *See Brown-Forman*, 476 U.S.; *Healy*, 491 U.S.

¹¹⁶ *Brown-Forman*, 476 U.S. at 575.

¹¹⁷ *Edgar v. MITE Corp.*, 457 U.S. 624, 642 (1982) (plurality opinion).

¹¹⁸ *Brown-Forman*, 476 U.S. at 583.

¹¹⁹ *Id.*

¹²⁰ *Healy*, 491 U.S. at 342.

¹²¹ *Id.*

¹²² *Id.*

¹²³ *Ass'n for Accessible Meds v. Frosh*, No. MJG-17-1860, 2017 WL 4347818 (D. Md. 2017) at 6.

to sign a Master Settlement Agreement.¹²⁴ Non-participating parties had to make an escrow payment on each cigarette sold “within the Commonwealth whether directly or indirectly through a distributor . . .”¹²⁵ The Fourth Circuit distinguished the case from other similar price parity decisions in *Healy* and *Brown-Forman* because the statute limited its applicability to only the sale of cigarettes “within the Commonwealth.”¹²⁶ According to the Fourth Circuit, the statute did not directly link the prices of cigarettes sold in the state with those sold outside of the state.¹²⁷ Consequently, the statute did not have the “practical effect” of controlling prices or transactions that occur completely outside of the Virginia.¹²⁸

Next, the United States District Court for Maryland addressed the Due Process vagueness challenge. Persuasive precedent in Maryland suggests that a law will not be void for vagueness if it “(1) establishes ‘minimal guidelines to govern law enforcement,’ and (2) gives reasonable notice of the proscribed conduct.”¹²⁹ There is no clear standard to apply to facial vagueness challenges.¹³⁰ “At the very least, it appears that a facial challenge cannot succeed if a ‘statute has a plainly legitimate sweep.’”¹³¹ A statute having a “plainly legitimate sweep” must have “more than a conceivable application.”¹³²

AAM argued that the statute did not define the terms “excessive”, “not justified” and “appropriate”, in relation to rising prices, requiring further explanation to sufficiently understand the terms.¹³³ The court ruled that in cases of broad terms, each phrase is context specific, and must be examined

¹²⁴ *Star Scientific Inc.*, 278 F.3d at 354.

¹²⁵ *Id.*

¹²⁶ *Id.* at 356.

¹²⁷ *Id.*

¹²⁸ *Id.*

¹²⁹ *Schleifer by Schleifer*, 159 F.3d at 853 (quoting *Elliot v. Administrator Animal & Plant Health Inspection Serv.*, 990 F.2d 140, 145 (4th Cir. 1993)).

¹³⁰ *Ass’n for Accessible Meds v. Frosh*, No. MJG-17-1860, 2017 WL 4347818 (D. Md. 2017) at 8.

¹³¹ *U.S. v. Comstock*, 627 F.3d 513, 518 (4th Cir. 2010) (quoting *Crawford v. Marion Cnty. Election Bd.*, 553 U.S. 181, 202 (2008)).

¹³² *Martin v. Lloyd*, 700 F.3d 132, 136-37 (4th Cir. 2012) (quoting *U.S. v. Comstock*, 627 F.3d 513, 518 (4th Cir. 2010)).

¹³³ Pl.’s Opp. Mot. Dismiss, *Ass’n for Accessible Meds v. Frosh*, No. MJG-17-1860, 2017 WL 4347818 (D. Md. 2017) at 12.

individually.¹³⁴ Here, the court found that it is “at least very plausible” that the combination of these broad terms could render the statute vague.¹³⁵

AAM further argued that the term “meaningful” is unconstitutionally vague.¹³⁶ The entire phrase, “no meaningful choice”, is qualified by two sub provisions: “(i) The importance of the drug to their health; and (ii) insufficient competition in the market for the drug.”¹³⁷ However, AAM did not challenge either of these sub provisions as vague. Ultimately, the court concluded that neither party provided an adequate record to resolve the vagueness issue.¹³⁸ The court held that AAM’s claim for vagueness was “at least plausible” and denied defendants motion seeking dismissal of the vagueness claims.

The unclear nature of the void for vagueness question caused the United States District Court for Maryland to fall short of a definitive answer with regards to HB 631.¹³⁹ The Supreme Court has held, as a general principle, that economic regulations receive a less strict vagueness test “because its subject matter is often more narrow,” and because businesses are expected to consult relevant legislation in advance of any action.¹⁴⁰ Maryland’s act should certainly fall within this category of economic regulations receiving a less strict vagueness test.

Many statutes often use broad terms, and courts have upheld some of these statutes against challenges for vagueness.¹⁴¹ While the Supreme Court and Maryland have little precedent on the term “unconscionable” in regards to vagueness challenges, other jurisdictions have taken up a vagueness challenge using the term in some form.¹⁴² In Massachusetts, the court upheld a

¹³⁴ *Ass’n for Accessible Meds v. Frosh*, No. MJG-17-1860, 2017 WL 4347818 (D. Md. 2017) at 11; *See also Francis v. Giacomelli*, 588 F.3d 186, 193 (4th Cir. 2009) (quoting *Bell Atl. V. Twombly*, 550 U.S. 544, 557 (2007)) (“A complaint must allege sufficient facts ‘to cross the line between possibility and plausibility of entitlement to relief.’”).

¹³⁵ *Ass’n for Accessible Meds v. Frosh*, No. MJG-17-1860, 2017 WL 4347818 (D. Md. 2017) at 9.

¹³⁶ Pl.’s Mot. Prelim. Inj., *Ass’n for Accessible Meds v. Frosh*, No. MJG-17-1860, 2017 WL 4347818 (D. Md. 2017) at 27-28.

¹³⁷ MD. CODE ANN., HEALTH § 2-801 (f) (2) (LexisNexis 2017).

¹³⁸ *Ass’n for Accessible Meds v. Frosh*, No. MJG-17-1860, 2017 WL 4347818 (D. Md. 2017) at 11.

¹³⁹ *Id.* at 11.

¹⁴⁰ *Village of Hoffman Estates v. Flipside*, 455 U.S. 489, 498, S. Ct. 1186, 1193, 71 L. Ed. 2d 362 (1982).

¹⁴¹ *See, e.g., Grayned v. City of Rockford*, 408 U.S. 104, 110 (1972) (upholding an anti-noise regulation that used the phrase “tends to disturb”); *United Companies Lending Corp. v. Sargeant*, 20 F. Supp. 2d 192, 205 (D. Mass. 1998) (rejecting a vagueness challenge where the phrase “otherwise unconscionable” was used but undefined.).

¹⁴² *See generally United Companies Lending Corp.*, 20 F. Supp. 2d at 205.

vagueness challenge using the term unconscionable.¹⁴³ In that case, a law established that a mortgage lender procuring a loan with rates or terms that significantly deviate from industry wide standards that are otherwise unconscionable would be guilty of unfair or deceptive trade practices.¹⁴⁴ However, the term “otherwise unconscionable” was never defined in the law.¹⁴⁵ This is in stark contrast to Maryland’s law, which at the very least attempts to further define the term “unconscionable increase”.¹⁴⁶

AAM appealed the District Court of Maryland’s dismissal of the Dormant Commerce Clause challenge to the statute, as well as their refusal to enjoin enforcement of the statutes for vagueness, to the United States Fourth Circuit Court of Appeals.¹⁴⁷ The Fourth Circuit reviewed the lower courts dismissal de novo, accepting all well pleaded allegations of AAM as true, and “drawing all reasonable inferences” in favor of AAM.¹⁴⁸ Arguments in the case took place on January 24, 2018, with the final decision being handed down on April 13, 2018.¹⁴⁹

Maryland first argued that the extraterritoriality principal put forth by the Supreme Court in *Walsh* was limited to price affirmation statutes.¹⁵⁰ The Court disagreed with this finding on the basis that Maryland’s interpretation of the language in that case was too narrow.¹⁵¹ Justices Agee and Thacker also rejected this notion, conversely holding that the Court’s statement on the principal of extraterritoriality is violated if the law at issue “regulates the price of any out-of-state transaction, either by its express terms or by its inevitable effect.”¹⁵² In *Walsh*, the Maine law at issue created a program where the state

¹⁴³ *United Companies Lending Corp.*, 20 F. Supp. 2d at 205.

¹⁴⁴ *Id.*

¹⁴⁵ *Id.* at 206 (quoting *Zapatha v. Dairy Mart, Inc.*, 408 N.E. 2d 1370, 1376 (Mass. 1980)).

¹⁴⁶ *Ass’n for Accessible Meds v. Frosh*, No. MJG-17-1860, 2017 WL 4347818 (D. Md. 2017) at *9-10.

¹⁴⁷ See generally *Ass’n for Accessible Meds v. Frosh*, 887 F.3d 664 (4th Cir. 2018).

¹⁴⁸ *Id.* at 667; See also *Schilling v. Schmidt Baking Co.*, 876 F.3d 569, 599 (4th Cir. 2017).

¹⁴⁹ See generally, *Ass’n for Accessible Meds*, 887 F.3d (4th Cir. 2018).

¹⁵⁰ *Ass’n for Accessible Meds*, 87 F.3d at 669; See generally *Pharmaceutical Research & Manufactures of America v. Walsh*, 538 U.S. 644, 669, 123 S.Ct. 1855, 155, L.Ed.2d 889 (2003)(holding that the rule applied in *Baldwin* and *Healy* did not apply to the rebate program at issue because “unlike price control or price affirmation statutes, ‘[the program] does not regulate the price of any out-of-state transaction, either by its express terms or by its inevitable effect.’”).

¹⁵¹ *Ass’n for Accessible Meds*, 87 F.3d at 670.

¹⁵² *Id.*; *Walsh*, 538 U.S. at 669, 123 S.Ct. 1855.

would “attempt to negotiate rebates with drug manufactures to fund the reduced price for drugs offered to [program] participants.”¹⁵³ To contrast, the court explained that in *Walsh*, the Maine law directly affected only transactions within Maine, and not the prices manufacturers could charge outside of the state.¹⁵⁴ Thus, the court found Maryland’s argument unpersuasive, and held that the extraterritoriality principle applied not only to price affirmation statutes, but also to any statute that regulates the price of any out of state transaction.¹⁵⁵

The Court next turned to the merits of AAM’s Dormant Commerce Clause challenge.¹⁵⁶ AAM first asserted that the law is not triggered by any sale that takes place solely within Maryland.¹⁵⁷ The United States District Court for Maryland found that the law passed the Dormant Commerce challenge because the provisions of the law are only triggered where there is a drug made available for sale in Maryland.¹⁵⁸ However, the Fourth Circuit disagreed with this interpretation, finding that the plain language of the law allows Maryland to enforce the law against parties in a transaction which may not have resulted in any drugs being shipped to Maryland.¹⁵⁹ The law defined “essential off-patent or generic drugs” as any drug “made available for sale in Maryland,” and prohibited manufacturers from using the defense that they never sold directly to any Maryland consumers.¹⁶⁰ The Court interpreted this language to allow the law to apply to sales which take place outside of Maryland, or resale transactions with non-Maryland consumers.¹⁶¹ In fact, Maryland admitted that the law was intended to reach sales upstream from consumer sales occurring in Maryland, meaning the law would potentially effect sales occurring outside of Maryland.¹⁶² The Court thus found that the District Court erred in relying on the “made available for sale” language when it upheld the law.¹⁶³

AAM next contended that the law will impact transactions that occur wholly outside of Maryland.¹⁶⁴ Again, the Court agreed with AAM’s

¹⁵³ *Id.* at 649.

¹⁵⁴ Ass’n for Accessible Meds, 87 F.3d at 670.

¹⁵⁵ *Id.*

¹⁵⁶ *Id.*

¹⁵⁷ *Id.*

¹⁵⁸ See generally *Ass’n for Accessible Meds v. Frosh*, No. MJG-17-1860, 2017 WL 4347818 (D. Md. 2017).

¹⁵⁹ Ass’n for Accessible Meds, 87 F.3d at 671.

¹⁶⁰ MD. Code Ann., HEALTH § 2-801 (b)(1)(iv) (LexisNexis 2017).

¹⁶¹ Ass’n for Accessible Meds, 87 F.3d at 671.

¹⁶² See Oral Arguments at 20:45-55, *Ass’n for Accessible Meds v. Frosh*, No. 17-2166 (4th Cir. Jan 24, 2018) (“The conduct that violates the statute could manifest itself in a wholesale transaction that occurs outside-of-state.”).

¹⁶³ Ass’n for Accessible Meds, 87 F.3d at 671.

¹⁶⁴ *Id.*

interpretation, given that the law's own terms measures the lawfulness of a price increase by the price the manufacturer or wholesaler charges in the initial sale of the drug.¹⁶⁵ This allowed manufacturers and wholesalers to regulate prices according to the initial sale of a drug, which may not have taken place in Maryland. Since the law did not allow retailers to be held liable, only manufacturers or wholesalers, the court found that the law specifically targeted the upstream pricing and sale of prescription drugs, which both parties agreed occurs mostly outside of Maryland.¹⁶⁶

Maryland saw the upstream pricing impact of a state regulation as a justification for the laws validity.¹⁶⁷ However, the court disagreed citing a similar statute in the *Freedom Holdings* case.¹⁶⁸ In that case, a New York statute banned the importation of cigarettes manufactured by companies that did not comply with a state escrow law.¹⁶⁹ The cigarette importers in this case argued that the New York law regulated out-of-state commerce by required manufacturers to sell higher priced cigarettes "to purchasers in sales transactions that occur wholly outside New York."¹⁷⁰ The Second Circuit disagreed, finding that the effects raised by the importers constitutes no more than incidental upstream pricing impact of a state regulation, and that "a similar pricing impact might result for any state regulation of a product."¹⁷¹ In *Freedom Holdings*, the Court ultimately held that price change caused by the New York law was the result of natural market forces, not artificially imposed by a law in another state.¹⁷²

In contrast, the Maryland law at issue attempted to impact prescription drug manufactures reaction to market increases, and regulate the prices the manufacturers charge for their drugs.¹⁷³ This, the Court held, is "more than an 'upstream pricing impact' – it is a price control", which is prohibited by the Commerce Clause.¹⁷⁴ The Fourth Circuit stated that Maryland can not, even pursuant to protecting its consumers from skyrocketing drug prices, impose

¹⁶⁵ Ass'n for Accessible Meds, 87 F.3d at 671.

¹⁶⁶ *Id.* (AAM challenges the law only as it pertains to the out of state sales.).

¹⁶⁷ *Id.* at 672.

¹⁶⁸ *Id.*; See generally *Freedom Holdings, Inc. v. Spitzer*, 357 F.3d 205, 220 (2d Cir. 2004).

¹⁶⁹ *Freedom Holdings, Inc. v. Spitzer*, 357 F.3d 205, 211-14 (2d Cir. 2004).

¹⁷⁰ *Id.* at 220.

¹⁷¹ *Id.*

¹⁷² *Id.*

¹⁷³ Ass'n for Accessible Meds, 87 F.3d at 672.

¹⁷⁴ *Id.*

price controls in this manner, finding that the district court erred by not accounting for this impact.¹⁷⁵

Finally, the court addressed the Act's burden on interstate commerce in prescription drugs.¹⁷⁶ Since the Act targeted specifically wholesales, and not retail pricing, the court found that a similar regulation imposed by another state could require prescription drug manufacturers to abide by conflicting state requirements.¹⁷⁷ If different states enacted a similar law, a manufacturer may initiate a transaction that is completely lawful in one state, yet be subject to enforcement by another state completely unrelated to the transaction.¹⁷⁸ If Maryland requires manufacturers to sell drugs at a certain price, but another state imposes a different price for the same drug, manufacturers could not possibly comply with both laws simultaneously for the same transaction.¹⁷⁹ If a drug sold to another state later became available for sale in Maryland, the Act permitted Maryland to penalize the manufacturer based on the price of the drug sold to another state.¹⁸⁰ The court found that these competing local economic regulations is the exact scenario the Commerce Clause was meant to preclude.¹⁸¹ As such, the Fourth Circuit ultimately reversed the district court's dismissal of the claims and remanded the case with instructions to enter judgment in favor of AAM, thus invalidating the Act.¹⁸²

In a last ditch effort to save the law, Maryland filed a writ of certiorari to the U.S. Supreme Court on October 19, 2018.¹⁸³ They first alleged that the Court's extraterritoriality cases concern economic protectionism, not efforts to protect consumers from predatory commercial practices.¹⁸⁴ Maryland also alleged that the price gouging ban is consistent with the Courts prior precedent on the matter, and that due to the confusion among circuits over the scope of the extraterritoriality principle, the Supreme Court should take the case.¹⁸⁵

¹⁷⁵ Ass'n for Accessible Meds, 87 F.3d at 673.

¹⁷⁶ *Id. Healy*, 491 U.S. at 336, 109 S.Ct. 2491 ("Generally speaking, the Commerce Clause protects against inconsistent legislation arising from the projection of one state regulatory regime into the jurisdiction of another State"); *Brown-Foreman*, 476 U.S. at 583-84, 106 S.Ct. 2080.

¹⁷⁷ *Id.*

¹⁷⁸ Ass'n for Accessible Meds, 87 F.3d at 673.

¹⁷⁹ *Id.*

¹⁸⁰ *Id.*

¹⁸¹ *Id.*

¹⁸² *Id.*

¹⁸³ *Frosh v. Ass'n for Accessible Medicines*, No. 18-546, 2018 WL 5307744 (U.S.) (cert. denied).

¹⁸⁴ *Id.*

¹⁸⁵ *Id.*

However, on February 19, 2019, the Supreme Court denied cert on the case, thus ending Maryland's long bid to uphold the law.¹⁸⁶

IV. SOLUTION

Over the years, several states have proposed solutions to the growing concern of rising prescription drug prices including state rebate systems and price caps on pharmaceutical drugs.¹⁸⁷ While the U.S. Supreme Court upheld the state rebate system, the Federal Circuit halted D.C.'s attempt to regulate pharmaceutical prices.¹⁸⁸ On the federal level, Congress killed an attempt to systematically import drugs from Canada in 2007; however, both the House and the Senate introduced new legislation in February of 2017 to increase competition in the pharmaceutical industry.¹⁸⁹ Each proposal tackles the issue of rising drug costs from a different angle and provides alternative methods to Maryland's failed approach.

A. *Maine and D.C. Approaches*

Maine has employed one of the most successful programs to date to combat rising drug prices.¹⁹⁰ The program operates in conjunction with Medicaid, a federal program offering financial assistance to states that reimburse medical costs for individuals who otherwise could not afford care.¹⁹¹ Medicaid utilizes a prior authorization program. In order "to reduce prescription drug prices for residents of the State," Maine utilized the prior authorization system with the Act to Establish Fairer Pricing for Prescription Drugs ("Maine Rx program").¹⁹² The program includes both patients on Medicaid and those not, limiting its availability to person with financial or medical need who don't "have a comparable or superior prescription drug benefit plan."¹⁹³

¹⁸⁶ *Frosh v. Ass'n for Accessible Meds*, 139 S.Ct. 1168 (2019).

¹⁸⁷ See ME. REV. STAT. ANN. tit. 22, § 2681 (2011); D.C. CODE ANN. §§ 28-4551 to 28-4555 (LexisNexis 2001 & Supp. 2008).

¹⁸⁸ See *Pharm. Research & Mfrs. of Am.*, 538 U.S. 644 (2003); *Biotechnology Indus. Org. v. Dist. Of Columbia*, 496 F.3d 1362, 1374 (Fed. Cir. 2007).

¹⁸⁹ See *Senate Kills Bid to Import Prescription Drugs*, MSNBC, (May 7, 2007), <http://www.nbcnews.com/id/18530709/#.WmyzXSMrLu0>; S. 297, 115th Cong. (2017); H.R. 749, 115th Cong. (2017).

¹⁹⁰ ME. REV. STAT. ANN. tit. 22, § 2681 (2004 & Supp. 2007).

¹⁹¹ *Pharm. Research & Mfrs. of Am.*, 538 U.S. at 650.

¹⁹² ME. REV. STAT. ANN. tit. 22, § 2681 (2004 & Supp. 2007).

¹⁹³ *Id.* at § 2681(2)(F).

The prior authorization program, established by the Omnibus Budget Reconciliation Act (“OBRA”) of 1990, authorized individual states to negotiate rebates from pharmaceutical manufacturers when purchased by a Medicaid user.¹⁹⁴ The rebates, paid by the pharmaceutical companies, directly fund the reduced drug prices for Maine Rx participants.¹⁹⁵ The drugs are only covered under Medicaid if the manufacturer has agreed to give a rebate.¹⁹⁶ If a manufacturer decides to reject the rebate, their drugs will be placed on a prior authorization list.¹⁹⁷ Medicaid will only pay for drugs on the prior authorization list if the physician proscribing the medicine gets authorization from the Medicaid system.¹⁹⁸ This provision is extremely undesirable to pharmaceutical manufacturers. Being placed in this list and forcing physicians to gain prior authorization could lead to doctors not proscribing that particular drug.

Maine’s Rx program is not as expansive as it could be to protect consumers. The law does not require manufacturers to join the program, which could lead to inaccessibility of some important drugs to consumers in need.¹⁹⁹ Additionally, the program does nothing for patients who do not qualify for the “financial and medical need” category, but still cannot afford to pay for their necessary drugs.²⁰⁰ Finally, even patients with insurance coverage experience large bills for expensive medication, which results in higher costs for the consumers.²⁰¹

In 2005, D.C. took a different approach than Maine’s rebate system, but was not as successful. The D.C. Excessive Pricing Act restricted the pricing of excessively priced patented pharmaceuticals.²⁰² This law differed from Maryland’s law in that it attempted to regulate only patented drugs. The law implemented a prohibition on drug manufacturers from selling patented prescription drugs which resulted in the drug being sold for an excessive price.²⁰³ While it was ground breaking at its time, the Federal Circuit Court of

¹⁹⁴ *Pharm. Research & Mfrs. of Am.*, 538 U.S. at 652.

¹⁹⁵ *Id.* at 649.

¹⁹⁶ *Id.*

¹⁹⁷ ME. REV. STAT. ANN. tit. 22, § 2681(7-A).

¹⁹⁸ *Pharm. Research & Mfrs. of Am.*, 538 U.S. at 653.

¹⁹⁹ Christopher Stambaugh, *State Price Control Laws Are the Wrong Prescription for the Problem of Unaffordable Drugs*, 12 Fordham Intell. Prop. Media & Ent. L.J. 897, 925 (2002).

²⁰⁰ *Id.* at 923.

²⁰¹ *Id.* at 924.

²⁰² D.C. CODE ANN. §§28-4551 to 28-4555 (LexisNexis 2001 & Supp. 2008)(repealed 2006).

²⁰³ *Id.* § 28-4553 (“any drug manufacturer or licensee thereof, excluding a point of sale retail seller, to sell or supply for sale or impose minimum resale requirements for a patented prescription drug that results in the prescription drug being sold in the District for an excessive price.”).

D.C. eventually struck down the law because federal patent laws preempted the Act.²⁰⁴

The D.C. Excessive Pricing Act's broad scope caused optimism among its supporters.²⁰⁵ The act allowed a plaintiff to establish a prima facie case of excessive pricing if the wholesale price of the patented drug in D.C. is over thirty percent higher than the price for the same drug in any "high income country" where the product also has a patent.²⁰⁶ High-income countries included the United Kingdom, Germany, Canada, and Australia.²⁰⁷ However, unlike Maryland's law, excessive pricing was never explicitly defined in the D.C. Excessive Pricing Act.²⁰⁸

B. Recent Federal Attempts

The recent trend of rising drug prices has also caught the attention of federal legislators. In 2017, two bills were introduced in both Houses aimed at increasing competition in the pharmaceutical industry in an attempt to drive down prices.²⁰⁹ Rather than outright prohibiting price hikes of pharmaceutical drugs, the bills attack some of the root causes of price hikes. Examples of these causes include long waits for the approval of an abbreviated new drug from the Food and Drug Administration ("FDA") causing a scarcity of certain drugs on the market, which in turn, drives prices up. These abbreviated drugs are generic forms of other patented drugs on the market, which increase competition.

The House's Lower Drug Costs through Competition Act and the Senate's Increasing Competition in Pharmaceuticals Act are largely similar in content.²¹⁰ There is a significant backlog of abbreviated new drug applications for generic drugs, which limits the options on the market.²¹¹ The bills outlines a general premise that improving the review procedures of abbreviated new

²⁰⁴ *Biotechnology Indus. Org.*, 496 F.3d at 1374.

²⁰⁵ Serena Lipski, Comment: Excessive Pricing And Pharmaceuticals: Why The Federal Patent Act Does Not Preempt State Regulation of Pharmaceutical Prices, 39 U. Tol. L. Rev. 913, 921 (2008) ("Due to the D.C. Excessive Pricing Act's broad scope, it had the potential to be a comprehensive and permanent solution to the high cost of pharmaceutical drugs").

²⁰⁶ D.C. Code Ann. §§28-4554(a)(LexisNexis 2001 & Supp. 2008).

²⁰⁷ *Biotechnology Indus. Org.*, 496 F.3d at 1365-66.

²⁰⁸ *Biotechnology Indus. Org.*, 496 F.3d at 1365.

²⁰⁹ See S. 297, 115th Cong. (2017).

²¹⁰ *Id.*

²¹¹ *Id.*

drugs would help improve competition and lower prices for patients, as well as establishing a clear timeframe for the FDA to expedite the review of certain applications when necessary.²¹²

The bills edit Chapter V of the Federal Food, Drug, and Cosmetic Act by adding the issuance of “Generic Priority Review Vouchers” for generic drugs to accelerate the long approval process.²¹³ The Secretary of Health and Human Services is directed to review the vouchers no later than 150 calendar days after the application has been submitted for review.²¹⁴ Additionally, the vouchers may be transferred between manufacturers, including by sale.²¹⁵ This could, for example, allow a manufacturer to transfer their voucher to a manufacturer of a different drug due to a shortage in supply of the drug on the market. The voucher system frees many generic drugs from sluggish bureaucracy, resulting in many more drugs hitting the market much faster than in the past. Though the bills have gained bipartisan support across the country, neither has passed its respective house.²¹⁶

C. *Increased Need For Federal Legislation*

Maryland tried and failed to implement a groundbreaking solution to protect its citizens from the dangers of rising drug costs. Other states took notice of Maryland’s attempt, and have attempted to following suit. Maryland’s law was groundbreaking in its own right, but only further complicated a greater federal regulatory scheme to bring down the prices of pharmaceutical drugs.

The program employed in Maine simply does not require enough accountability from manufacturers for Maryland to adopt a similar plan. For instance, Maine’s Rx program does not require manufacturers to enter into rebate agreements. By not entering the agreement, the drug is placed on a prior authorization list, requiring the doctor to get approval from Medicaid. This, theoretically, discourages doctors from prescribing that particular drug due to the extra prior authorization step. However, while many of these manufacturers are national, some are international companies which do business all over the world. A decrease in orders for a specific drug in one state, or even two is unlikely to have any appreciable effect on these large companies.

As this issue gained greater national attention, it become more apparent that overarching federal legislation on the issue of pharmaceutical drug pricing is necessary to increase competition in the generic drug market specifically, and

²¹² See S. 297, 115th Cong. (2017).

²¹³ *Id.*

²¹⁴ S. 297, 115th Cong. (2017); H.R. 749, 115th Cong. (2017).

²¹⁵ *Id.*

²¹⁶ *Id.*

help drive prices down overall. President Donald Trump has proposed new initiatives to help lower drug prices.²¹⁷ Additionally, his 2016 Presidential opponent, Hillary Clinton, outlined a plan to combat “Unjustified price hikes for Long-Available Drugs.”²¹⁸ In March of 2017, Rep. Elijah Cummings of Maryland and Rep. Peter Welch of Vermont met with President Trump in the White House to discuss this issue, however, nothing has materialized from the conversation. These attempts illustrate the desire to find a solution on the federal level.

In order to create uniformity among the states, the federal government must tackle this issue head on. To date, we have seen a few examples of individual states attempting to take on this legislation, which usually results in lengthy litigation.²¹⁹ If this troubling trend continues, we could be left with individual states, and subsequently Federal Circuits, determining which programs work and which ones don’t. The varying political opinions of the circuits could lead to more regulation in certain places than in others, making it harder for manufacturers to follow the different laws of each given state. State by State solutions would only hinder the overall mission to decrease pharmaceutical prices and allow access to more affordable drugs for all Americans.

D. A Potential Solution for Maryland

In response to Maryland’s efforts, states around the country have attempted to help curb rising prescription drug costs one way or another.²²⁰ Many have looked to Maryland’s approach to facilitate their own lawmaking process.²²¹

²¹⁷ See generally Office of Health and Human Services, American Patients First (May 2018), <https://www.hhs.gov/sites/default/files/AmericanPatientsFirst.pdf>; See also Robert Pear, Trump Proposes to Lower Drug Prices by Basing Them on Other Countries’ Costs, THE NEW YORK TIMES (Oct. 25, 2018), <https://www.nytimes.com/2018/10/25/us/politics/medicare-prescription-drug-costs-trump.html>.

²¹⁸ Hillary’s Plan to Respond to Unjustified Price hiked for Long-Available Drugs, WASHINGTON POST BLOG (January 14, 2018 10:15 AM), <https://www.washingtonpost.com/blogs/wonkblog/files/2016/09/DrugPricingPlan.pdf>.

²¹⁹ See *Ass’n for Accessible Meds v. Frosh*, No. MJG-17-1860, 2017 WL 4347818 (D. Md. 2017); *Pharm. Research & Mfrs. of Am.*, 538 U.S. 644 (2003); *Biotechnology Indus. Org.*, 496 F.3d 1362 (Fed. Cir. 2007).

²²⁰ See generally State Legislative Action on Pharmaceutical Prices, NATIONAL ACADEMY FOR STATE HEALTH POLICY (March 7, 2018), <https://nashp.org/wp-content/uploads/2016/09/Rx-Legislative-Tracker-2017-Final.pdf>.

²²¹ Green & Padula, *supra* note 12.

However, with no current federal legislation in place, Maryland should take steps to improve their failed law.

Maryland could benefit tremendously from amending the law to reduce ambiguities with its enforcement. In California, the legislature recently passed a drug transparency law attempting to combat the same problem as Maryland.²²² California's law requires pharmaceutical companies to notify the state and health insurers of a rise in price of their medication of 16 percent or more over a two-year period.²²³ Additionally, companies will be required to provide justification of the increase to California's Office of Statewide Health Planning and Development.²²⁴ The law faced similar backlash to the law in Maryland, with drug companies challenging the legislation almost immediately, and is currently still pending litigation.²²⁵

Maryland could either try to pass new legislation or simply amend their failed law in order to catch price rises before they affect Maryland consumers. In regards to the first option, Maryland could follow California's lead by adopting a law that works in conjunction with a new version of their recently failed law and requires companies to give notice when a raise in prices is coming. Under the recently repealed law, Maryland's AG made the determination of whether or not a drugs price hike is unconscionable. This determination would take time and force consumers to pay the raised price until that determination is made. By passing a similar transparency law to California, the AG would be notified before the price hike, and could make the determination of whether or not the rise in price is unconscionable before the law takes effect. This method could also save the State money by limiting the number of law suits brought on behalf of Maryland residents against these large manufacturing companies, most of whom likely have large capital to expend on legal fees.

The MD Price Gouging Act was a start, but not the solution to the country's need to ultimately allow for federal legislation. In the 1970's, pharmacies

²²² See New California law limits drug manufacturer co-pay and other discounts in California, HOGAN LOVELLS (Mar. 8, 2018), https://www.hoganlovells.com/~media/hogan-lovells/pdf/2017/2017_10_16_health_alert_new_california_law_limits.pdf?la=en.

²²³ April Dembosky, California Governor Signs Law To Make Drug Pricing More Transparent, NPR (Mar. 8, 2018), <https://www.npr.org/sections/health-shots/2017/10/10/556896668/california-governor-signs-law-to-make-drug-pricing-more-transparent>.

²²⁴ *Id.*

²²⁵ Tracy Seipel, Drug companies sue California over drug pricing transparency law, THE MERCURY NEWS (Mar. 1, 2018), <https://www.mercurynews.com/2017/12/08/drug-companies-sue-california-over-drug-pricing-transparency-law/>.

substitution of brand name drugs in favor of generic drugs was illegal in most of the country.²²⁶ In response, Kentucky filed controversial law allowing the practice or substitution patented drugs for generic drugs in their state.²²⁷ Similar laws began to be passed nationwide, and within eight years, generic drug substitution became federal law.²²⁸ Similarly since the passage of Maryland's law, sixteen other states have passed laws either addressing price gouging, or calling for better transparency from drug companies with regards to their price hikes.²²⁹ With their recent attempt at a law combating this issue, Maryland could have laid the groundwork for a similar path to federal legislation.

V. CONCLUSION

The need for federal legislation on this issue has never been greater. In the United States, nine out of every ten prescriptions filled are for a generic drug.²³⁰ The limited availability of these drugs, which quite literally save lives every day, should be a crime in its own right. Approaching the issue on a state-by-state basis could prove to work in the long run, but could also only further complicate compliance from many pharmaceutical companies due to the varying laws by state. That is why federal legislation is needed to allow increased, and in some instances expedited access to important generic drugs. With more options available on the market, drug prices will be driven down to the benefit of millions.

²²⁶ Green & Padula, *supra* note 12.

²²⁷ *Id.*; See generally KRS 217.822.

²²⁸ *Id.*

²²⁹ *Id.*

²³⁰ Generic Drugs, U.S. FOOD AND DRUG ADMINISTRATION (Jan. 28, 2018 3:30 PM), <https://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/GenericDrugs/default.htm>.